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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,637	04/27/2001	Anthony Robert Milnes Coates	Q-64007	9237

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/842,637	Applicant(s) Coates et al.,
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 25, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-7, 9, and 10* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-7, 9, and 10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *8,9*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment and election without traverse of Group III, directed to a process of assessing antibacterial activity or isolating a test compound, filed 7/30/02 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague, indefinite and confusing in that the "assessing" step does not set forth the manner in which "antibacterial effects" are to be determined for any and all bacteria in this context. For example, the concentration of the material to be assessed is not set forth or the level of "effect" to be monitored and how.

Claim 9 is confusing in including an optional isolation step of a compound or agent "exhibiting antibacterial activity". It is noted that the nature and source of the agent remain unidentified. In addition, there is no indication as to whether such an "agent" is an isolated compound or a complex gemisch of material. Therefore, it is uncertain how such a gemisch is to be "isolated" In this regard it is unclear what constitutes a "test ... agent" and the nature thereof is unclear in this context. Also the extent of "exhibiting antibacterial activity" cannot be readily ascertained in this context.

Claim 10 fails to find proper antecedent basis in claim 9 for "the identified agent or compound". There is no "identification" step in claim 9.

Claim 10 is vague, indefinite and confusing in the "step of amplifying" an unknown agent or compound, even though the compound or agent is indicated as "identified". How is it "identified" and how is a compound or agent "amplified"? For example, how is penicillin "amplified"? The process steps recited fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague indefinite and confusing in that in the preparation aspect the claim does not specify with any particularity how the selection of phenotypically antibiotic-resistance subpopulation is to be effected, except to indicate treatment with "at least one antibiotic". There is no indication regarding the concentration and nature of the antibiotic(s) or the nature or concentration of the bacteria to be treated to obtain the resistant subpopulation. Is this a single strain or a mixed culture? Also, the concentration of at least one antibiotic which is indicative of "resistance" is not set forth with any particularity. The assessment of the effects on a mixed culture of bacteria of a mixture of antibiotics would not be expected to be readily achievable.

Claim 3 is vague, indefinite and confusing in that the antecedent basis in claim 9 for the antibiotic and bacterial concentration is uncertain. Is this the concentration required to produce a resistant population or the concentration tested?

Claims 5-7 are vague, indefinite and confusing in that the antecedent basis in claim 9 for "said antibiotic" is uncertain. Is this the material to which resistance is selected or is this the material tested? In addition, it is apparent that strains of *E. coli, S. aureus* and *M. tuberculosis* resistant to kanamycin, ampicillin and rifampicin are already known to those of skill in this art and clinically available. Clarification is required.

Therefore, the metes and bounds of the claims are undefined.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahm et al. taken with Pelczar, George *et al.*, Shomura *et al.* and Barth.

The claims are directed to a process of assessing antibiotic susceptibility on resistant bacteria, wherein resistant bacteria are prepared by treating stationary cultures to select for resistant bacteria.

Sahm *et al.* disclose a process of assessing antibiotic susceptibility on resistant bacteria, wherein resistant bacteria are tested with various antibiotics (See, e.g., tables I and II).

The reference differs from the claimed invention in that the selection of resistant bacteria from stationary cultures is not disclosed. However, methods of selecting for bacteria resistant to antibiotics are old and well known in the art as adequately demonstrated by the Pelczar *et al.* (See, e.g., pages 373-374). In addition, George *et al.* disclose a process for obtaining resistant bacterial cells wherein the cells are grown to stationary phase (See, e.g., page 532, col. 1).

The references also differs from the claimed invention in that *E. coli* resistant to kanamycin and *S. aureus* resistant to ampicillin are not specifically disclosed. However, Shomura *et al.* disclose a screening test for antimicrobial agents effective against resistant bacteria wherein kanamycin resistant *E. coli* are taught (See, e.g.,col. 4, lines 35-38) and Barth disclose a screening test for antimicrobial agents effective against resistant bacteria wherein ampicillin resistant *S. aureus* are disclosed. (See, e.g.,col. 14, lines 5-8).

With respect to the "amplification" process of claim 10, Shomura *et al.* provide guidelines about maximizing the producing of the compound of interest, which is deemed to constitute "amplification" as claimed. (See, e.g., Examples 1 and 2).

One of ordinary skill in the art would have had a reasonable expectation of success in applying the screening tests taught by Sahm *et al.* to a variety of resistant bacteria produced according to the method disclosed by Pelczar *et al.*. Alternatively one of ordinary skill in the art would have had a reasonable expectation of success of assessing the effectiveness of antimicrobial agents using already known strains of antibiotic resistant bacteria, such as kanamycin-resistant *E. coli.* or ampicillin resistant *S. aureus*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Sahm *et al.* by assessing the effectiveness of antimicrobial agents on a large variety of bacteria wherein resistance is induced by the method of Pelczar *et al.* or by assessing effectiveness on already existing resistant bacteria, such as kanamycin resistant *E. coli* as taught by Shomura *et al.* and ampicillin resistant *S. aureus* as disclosed by Barth for the expected benefit of effective chemotherapeutic agents and thus

increasing the success and efficiency of the treatment dangerous bacterial infections caused by antibiotic resistant bacteria in susceptible individuals to avoid bacteremia or other complications.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahm *et al.* taken with Pelczar *et al.*, Shomura *et al.* and Barth as applied to claims 2-4, 6-7 and 9-10 above, and further in view of Murray *et al.* and *The Merck Index.*

The references are discussed above.

The invention as claimed differs from the references in that rifampicin resistant *M. tuberculosis* is not disclosed. However, Murray *et al.* adequately demonstrate that rifampicin resistant strains are old and well known in the art. (See, e.g., page 428). Also *The Merck Index* discloses that rifampin and rifampicin are one and the same (See, e.g., item 8382).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Sahm *et al.* by assessing the effectiveness of antimicrobial agents on a large variety of bacteria wherein resistance is induced by the method of Pelczar *et al.* or by assessing effectiveness on already existing resistant bacteria, such as kanamycin resistant *E. coli* as taught by Shomura *et al.* and ampicillin resistant *S. aureus* as disclosed by Barth or rifampicin resistant *Mycobacterium tuberculosis,* as taught by Murray *et al.* for the expected benefit of identifying effective chemotherapeutic agents and thus increasing the success and efficiency in the treatment of tuberculosis, a dangerous and increasingly prevalent bacterial infection caused more and more by antibiotic resistant *Mycobacterium tuberculosis* in susceptible individuals.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Primary Examiner
Art Unit 1651